K134008

APR 0 9 2014

510(k) Summary

Summary of safety and effectiveness of MD Flex Heavy body Impression material

1. 510(k) Submitter:

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2. Company Contact: Ian Yun
   Title: Sales Director

3. Date of Submission 12/02/2013

4. 510(k) Preparer:

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USA
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5. Device Name and Classification:

Trade name	MD-Flex Heavy Body
Common name	Hydrophilic polyvinylsiloxane Impression material
Classification name	Material, Impression
Regulation number	872.3660
Class	II
Product Code	ELW

6. Predicate Devices:

Manufacturer	Discus Dental, Inc.
Device	Precision VPS Impression Material
510(k) Number	K040053
Manufacturer	Heraeus Kulzer, LLC
Device	Flexitime Xtreme 2 Heavy Tray
510(k) Number	K101617

7. Device Description:

MD-flex Heavy body is hydrophilic Polyvinylsiloxane Impression Material with thixotropic property, dimensional accuracy and excellent recovery from deformation. It complies with the requirements of ISO 4823:2000 Type 1 for dental elastomeric impression materials. It is supplied as a two-part base/catalyst formulation preloaded in a dual-barrel cartridge.

The MD Flex Heavy Body package includes two dual-barrel 50 ml cartridges, and six mixing tips that allows for easy mixing of the base and catalyst. The device (cartridge) and accessories (mixing tip) are to be sold non-sterile. Testing demonstrates that MD-Flex has a shelf life 2 years from the manufacturing date.

MD-Flex can be used to make a mold of a patient teeth and alveolar ridges. The mold can be used to generate Gypsum model within 30 minutes of removal of the mold from patient's mouth. The Gypsum model will be effectively reproduced without transformation due to an excellent reproducibility and volume stability of MD Flex.

8. Intended Use:

MD-flex Heavy Body is used to record the shape of the patient's teeth and alveolar ridges.

9. Biocompatibility:

Based on the contact duration listed in Appendix A of the Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" the following three biocompatibility tests Cytotoxicity, Irritation and Sensitizations test were conducted in compliance with ISO 10993. The test results included in section 10 demonstrate that MD-Flex Heavy Body is biocompatible.

10. Substantial Equivalence

Based on the fact that: MD Flex has nearly identical intended use and indications for use as the predicate, and; MD Flex demonstrates similar physical and chemical properties and performance characteristics as the predicates, Metabiomed Inc., concludes that MD-Flex Heavy Body is substantially equivalent to the predicate devices.

11. Conclusion

Based on performance testing and product description Metabiomed Inc. concludes that MD Flex Heavy Body is substantially equivalent to Precision VPS impression material and Flextime Xtreme 2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2014

Metabiomed, Incorporated
C/O Mr. Blix Winston
Correspondent
ACMD Consulting, LLC
2600 Mullinix Mill Road
Mt. Airy, MD 21771

Re: K134008
Trade/Device Name: MD-Flex Heavy Body
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression material
Regulatory Class: II
Product Code: ELW
Dated: January 16, 2014
Received: January 17, 2014

Dear Mr. Winston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3: Indications for Use Statements

Indications Statement for MD-Flex Heavy Body is included in this 510(k) application.

Indications for Use

510(k) Number (if known): K134008

Device Name: MD-Flex Heavy Body

Indications for Use:

MD-flex Heavy Body is used to record the shape of the patient's teeth and alveolar ridges.

Prescription Use ✔ AND/OR Over-The- Counter Use _____

(Part 21 CFR 810 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THUS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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